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Orthopedic Source Press-fit Hip
510(k) Summary
April 14, 2006

JUL 18 2006

Submitter
Orthopedic Source, Inc.
20501 Ventura Blvd.
Suite 225
Woodland Hills, CA 91364

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name Orthopedic Source Press-fit Hip

Common name Press-fit hip

Classification name Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
Per 21 CFR Sec. 888.3358

Product Code LPH

Equivalent Device Taperloc Hip (Biomet, K921301)

Device Description
The Orthopedic Source stem is manufactured from Ti-6Al-4V alloy that conforms to ASTM F136. It is a collarless flat wedge-shaped implant that provides excellent durability and stability in a design that is relatively simple and predictable to implant. The use of a collarless design in the Orthopedic Source hip tends to allow for self seating of the implant and achievement of optimal rotational stability, immediately after implantation. The incorporation of standard and lateralized offset options provides the surgeon the ability to reconstruct a stable joint with proper leg length in virtually all patient anatomies. The Orthopedic Source Stem has a 135° neck-shaft angle and a standard 12/14 Morse type taper is incorporated in to the geometry to receive modular heads. The proximal body is circumferentially coated with commercially pure titanium plasma spray. Femoral heads are manufactured from wrought CoCrMo alloy conforming to ASTM F799 and are available in 22m, 28mm and 32mm diameters and multiple neck lengths.

Intended Use
The Orthopedic Source Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because of: degenerative joint disease, including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. It is intended for cementless use.

Summary of Technological Characteristics Compared to Predicate Device
The results of an engineering analysis shows that the strength of the Orthopedic Source 7.5mm Offset Hip is slightly greater than the Taperloc 7.5mm Hip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Orthopedic Source, Inc.
c/o J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, Texas 78681

Re: K061124
Trade/Device Name: Orthopedic Source Press-fit Hip
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: June 5, 2006
Received: June 29, 2006

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

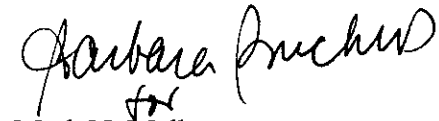
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061124

Indications for Use

510(k) Number (if known): _____

Device Name: Orthopedic Source Hip System

Indications for Use:

1) noninflammatory degenerative joint disease including osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of nonunion, femoral neck fractures of the proximal femur with head involvement that are unmanageable using other techniques.

This implant is intended for cementless use.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brechner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061124